Washington State Department of Health

ELABORATIONS

News and Issues for Washington's Clinical Laboratories

Volume VII Issue 4 May 2002

Use of Whole Blood Glucose Monitoring Devices in the Professional Setting

by Kathy LaBeau

More than half (55%) of the 2700 medical test sites licensed in Washington State indicate they use a CLIA-waived, whole blood glucose monitoring device (cleared by the FDA for home use) in their health care setting. With the popularity of these devices, we often receive questions about their use:

- What are appropriate uses of these home use devices in the professional setting?
- Can they be used for screening or diagnosis of diabetes, in addition to patient monitoring?
- Can plasma or serum be used on these devices?
- What should be done for quality control?

In this article, we share excerpts from recent American Diabetes Association (ADA) Position Statements[1, 2] and Reports[3] that describe the use of whole blood glucose monitoring devices and traditional laboratory testing in the screening for, and diagnosis and monitoring of, diabetes.

In an ADA Position Statement[1] on recommendations for screening for type 2 diabetes in physicians' offices and other health care settings, the authors make a distinction between diagnostic testing and screening. "The best screening test for diabetes, the fasting **plasma** glucose (FPG), is also a component of diagnostic testing." "An FPG ≥ 126 mg/dl is an indication for retesting, which should be repeated on a different day to confirm the diagnosis." The authors state "Capillary blood glucose testing using a reflectance blood glucose meter has also been used but because of the imprecision of this method, it is better used for self-monitoring rather than as a screening tool." They also say that "Separate diagnostic tests using standard criteria are required after positive screening tests to establish a definitive diagnosis."

The diagnostic criteria[1, 3] for diabetes mellitus (DM), gestational diabetes mellitus (GDM), impaired fasting glucose (IFG) and impaired glucose tolerance (IGT) are all based on the "Laboratory measurement of **plasma** glucose concentration . . . performed on venous samples with enzymatic assay techniques."

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Practice Guidelines

The following practice guidelines have been developed by the Clinical Laboratory Advisory Council. They can be accessed at the following website:
www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Anemia	Point-of-Care Testing
ANA	PSA
Bleeding Disorders	Renal Disease
Chlamydia	STD
Diabetes	Thyroid
Hepatitis	Tuberculosis
HIV	Urinalysis
Lipid Screening	Wellness

Glucose Monitors, continued from page 1

The product inserts of some glucose monitoring test strips (marketed for professional use) specifically warn the user not to use the test system to diagnose, i.e., "For *in vitro* diagnostic use in **monitoring** glucose levels. Do NOT use for diagnosis."

Whole blood capillary monitors are designed to be used only with **whole blood** specimens, not plasma or serum. The product inserts of some glucose monitoring systems warn the user about this, i.e., "Do NOT use plasma or serum as a test sample. Inaccurate results will be obtained."

The ADA Position Statement "Tests of Glycemia in Diabetes"[2] addresses patient and physician/laboratory-based testing used in monitoring the glycemic status of people with diabetes. "... because laboratory methods measure **plasma** glucose, many blood glucose monitors approved for home use and some test strips now calibrate blood glucose readings to plasma values. Plasma glucose values are 10-15% higher than whole blood glucose values, and it is crucial that people with diabetes know whether their monitor and strips provide whole blood or plasma results."

"ELABORATIONS" is a free monthly publication of the Washington State Department of Health (DOH) Public Health Laboratories (PHL) and Office of Laboratory Quality Assurance (LQA).

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NOTE: Letters to the editor may be published unless specified otherwise by the author.

Website addresses:
DOH home page: http://www.doh.wa.gov
LQA home page:
http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm

Manufacturers' product inserts may state how the instrument or strip values are calibrated, i.e., "The . . . system is plasma-calibrated . . ." or "The . . . Blood Glucose Meters . . . report a plasma-calibrated glucose result." Be sure to check your product insert to see how your instrument or strips are calibrated. If you cannot determine this information from the product literature, call your device manufacturer to find out.

This ADA Position Statement also states "Comparisons between results from patient self-testing of blood glucose in the clinic and simultaneous laboratory testing are useful to assess the accuracy of the patient results. If such testing is performed by health care providers using portable capillary blood testing devices rather than standard hospital or clinic laboratory methods, rigorous quality control procedures should be used. Participation in . . . voluntary proficiency testing program for home-use testing devices is recommended."

According to the Washington Medical Test Site Rules, you must follow the manufacturers' instructions for performance of tests categorized as "waived." This includes following any instructions about the testing of quality control samples or other quality assessment activities. To maintain good laboratory practices and follow the American Diabetes Association recommendations, test quality control samples on a regular basis to assess the accuracy of your whole blood glucose test results.

References:

1) American Diabetes Association. Screening for Diabetes [Position Statement]. Diabetes Care 2002 25: 21-24.
2) American Diabetes Association. Tests of Glycemia in Diabetes [Position Statement]. Diabetes Care 2002 25: 97-99.
3) American Diabetes Association. Report of the Expert Committee on the Diagnosis and Classification of Diabetes Mellitus. Diabetes Care 2002 25: 5-20.

These documents can be downloaded and printed from the following website: www.diabetes.org
Click on "For Health Care Professionals"
Click on "Clinical Practice Recommendations"

2002 Proposed MTS License Fee Changes

by Gail Neuenschwander

Many clinical laboratories in Washington will be faced with higher license fees when the Medical Test Site (MTS) licenses are renewed in 2002. The fee increase is needed due to an increase in the yearly fee that the state pays to the federal government for exemption from the federal Clinical Laboratory Improvement Amendments (CLIA) program. The reasons behind the fee increase were discussed in detail in past issues of *Elaborations* (September 1999 and March 2001). Stakeholder meetings were held throughout Washington in April and May of 2001 to discuss the fee increase with licensees and interested parties. Past issues of *Elaborations* can be found on the Laboratory Quality Assurance (LQA) website: http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm.

The 2002 Washington State Legislature approved the proposed fee increase in its recent session. The new fees will generate sufficient income to maintain the Washington State MTS program. The proposed 2002 fee schedule (see table on page 5) will match the current federal CLIA fee structure.

Revision of MTS Fee Rule (WAC 246-338-020, 246-338-090): A public hearing will be held on May 21, 2002 (see box below). At the hearing you will have an opportunity to comment on the proposed fee increase, or you can send written comments by May 14, 2002 to Yvette Lenz (address below) or FAX (360) 705-6654. The Target Plaza is a barrier-free-facility. Anyone planning to attend this hearing who requires a sign language interpreter or needs the material in an alternative format may contact Yvette Lenz at (360) 705-6652, TDD (800) 833-6388 by May 14, 2002, so arrangements can be made to meet those needs.

NOTICE OF PUBLIC HEARING

Location: Department of Health – Target Plaza Training Room
2725 Harrison Avenue NW
Olympia, WA 98502

Date: May 21, 2002
Time: 10:00 a.m.

2002 MTS License Renewal: All MTS licenses will expire on October 31st of this year. License renewal applications will be mailed in July and August 2002. The new fee schedule will be in effect when the MTS licenses are renewed.

If you have questions or comments, please contact Gail Neuenschwander at (206) 361-2805 or email Gail.Neuenschwander@doh.wa.gov.

2002 Proposed MTS License Fees

		Current MTS Fee	July 2002 MTS Fees
Certificate of Waiver		$ 108	**$ 150**
PPMP		$ 163	**$ 200**
(Nonaccredited)	**# of Tests**		
Limited Testing	1-750	$ 543	**$ 450**
Low Volume	751-2,000	$ 1,086	**$ 450**
A	2,001-10,000	$ 1,629	**$ 1,364**
B (>3 specialties)	2,001-10,000	$ 1,955	**$ 1,769**
C	10,001-25,000	$ 2,281	**$ 2,454**
D (>3 specialties)	10,001-25,000	$ 2,715	**$ 2,818**
E	25,001-50,000	$ 3,259	**$ 3,382**
F	50,001-75,000	$ 3,802	**$ 4,187**
G	75,001-100,000	$ 4,453	**$ 4,991**
H	100,001-500,000	$ 5,105	**$ 5,835**
I	500,001-1,000,000	$ 5,432	**$ 10,369**
J	>1,000,000	$ 5,974	**$ 12,443**
(Accredited)			
Limited Testing	1-750	$ 325	**$ 165**
Low Volume	751-2,000	$ 325	**$ 165**
A	2,001-10,000	$ 325	**$ 211**
B (>3 specialties)	2,001-10,000	$ 325	**$ 231**
C	10,001-25,000	$ 325	**$ 531**
D (>3 specialties)	10,001-25,000	$ 325	**$ 559**
E	25,001-50,000	$ 325	**$ 787**
F	50,001-75,000	$ 325	**$ 1,254**
G	75,001-100,000	$ 325	**$ 1,722**
H	100,001-500,000	$ 325	**$ 2,227**
I	500,001-1,000,000	$ 325	**$ 6,428**
J	>1,000,000	$ 325	**$ 8,168**

NOTE: Under the new fee schedule, **each CBC parameter** (RBC, WBC, hemoglobin, hematocrit, platelets, differential) **will be counted as separate tests** as they are under CLIA.

Plan of Correction

If you receive a deficiency during an on-site inspection, you must submit a plan of correction (POC) to the Office of Laboratory Quality Assurance (LQA) stating how the deficiency will be corrected. The POC must contain a correction statement for each deficiency sited. Each correction statement must include the following:

HOW the deficiency will be corrected
WHO is responsible for making the correction
WHAT will be done to prevent reoccurrence and monitor for compliance and
WHEN the corrections will be completed.

Changes – Changes – Changes!!

The Medical Test Site (MTS) Rules are contained in Washington Administrative Code (WAC) 246-338. Section 026 of this WAC defines the Notification Requirements for those facilities licensed as a MTS. The following are excerpts from this section of the WAC;

"The owner must notify the department (Department of Health/LQA) in writing at least thirty days prior to the date of opening or closing the medical test site". In addition, "the owner must notify the department in writing within thirty days of any changes in:

name of site;
director;
location of site;
tests, specialties and subspecialties; and
test methodologies".

For a full copy of the WAC, please refer to the LQA website at: http://www.doh.wa.gov/hsqa/fsl/LQA_Home.htm.

RECEIVING MULTIPLE ISSUES??

If you are receiving multiple issues of this newsletter it is because your name appears as the contact person for multiple Medical Test Site (MTS) licenses. Please share these copies with the staff at your various locations. The mailing list for ELABORATIONS is obtained directly from the MTS database so it is not possible to eliminate the duplicate copies without deleting the license for that MTS site. If another name should be added as the contact person for a particular facility, contact Vicky Terry at the Laboratory Quality Assurance Office at (206) 361-2802. Thank you for your understanding!

Waived Testing Helpful Hints

Make sure that your test kit and/or product insert states it is "CLIA-waived."

√ For some tests (defined in the regulations), all are classified as waived (i.e., fecal occult blood).

√ For some tests, only certain specific test systems are waived (i.e., Strep antigen).

√ In some cases, a test kit may be classified as waived or moderate complexity, depending on the type of specimen tested (i.e., some mononucleosis test kits are classified as waived when testing whole blood, but moderate complexity when testing serum or plasma).

NOTE: Check this spot in future editions of Elaborations for more helpful hints with waived testing.

Calendar of Events

PHL Training Classes:

Urine Sediments

May 8	Shoreline
May 9	Shoreline

Waived Testing Exhibition

June 21	Shoreline

Northwest Medical Laboratory Symposium
October 16 - 19 Portland

9th Annual Clinical Laboratory Conference
November 11 Seattle

2003 WSSCLS/NWSSAMT Spring Meeting
April 24-26, 2003 Pasco

Contact information for the events listed above can be found on page 2. The Calendar of Events is a list of upcoming conferences, deadlines, and other dates of interest to the clinical laboratory community. If you have events that you would like to have included, please mail them to ELABORATIONS at the address on page 2. Information must be received at least one month before the scheduled event. The editor reserves the right to make final decisions on inclusion.

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